REMARKS

Introductory Comments

An amendment was submitted on June 21, 2004 for the instant application, with a three-month extension of time therefor. This June 21, 2004 amendment was inadvertently submitted. Please substitute the June 21, 2004 amendment for the amendment herein.

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 10-16, 33, 35, 38 and 39 are pending and under consideration. Claims 23-32 and 34 are withdrawn due to the restriction requirement. Claims 10, 11, 15, 33, 38 and 39 have been amended as discussed below. No new matter has been added as a result of these amendments.

Applicants thank the Examiner for withdrawing the rejection under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 10-16, 33, 35, 38 and 39 Under 35 U.S.C. § 112, First Paragraph

Claims 10-16, 33, 35, 38 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner reiterates his position made in the previous Office Action, that the claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The Examiner states that this is because there is a very large number of variants in the genus since the claims

only require 50% identity to a nucleotide sequence. Applicants respectfully traverse the rejection. Applicants submit that the large number of variants in a claimed genus does not give rise to the conclusion that Applicants did not have possession of the claimed invention since the determination of percent identity is known to one of ordinary skill in the art, as argued in Applicants' previous response. Those arguments are incorporated herein.

However, in an effort to expedite prosecution of the instant application, the claims have been amended to render the rejection moot. Specifically, Applicants have amended the claims to recite "85% identity" instead of "50% identity" to the claimed SEQ ID NOS: 15 and 16. Support for this amendment can be found on page 14, lines 2-5 and page 24. Also noted on page 12 of the Office Action, the scope of the genus can be determined by the functional requirement of "catalytic activity". Applicants have described in the specification that the polynucleotides of the instant claims (1) contain open reading frames from which an immunogenic activity may be derived from, and (2) encode the polypeptides of the instant claims (page 12, lines 10-18). Additionally, it is disclosed that the high percentage of identity between the instant polynucleotides and the target polynucleotides allows hybridization of the polynucleotides of the instant claims (page 24, lines 23-25). All of these characteristics and activity are considered "catalytic activities". Therefore, Applicants submit that the specification discloses the "catalytic activity" as a functional requirement of the claimed polynucleotides, therefore describing the genus of the instant polynucleotide clearly in the specification as required.

The inquiry into whether the description requirement is met is determined on a case-by-case basis and is a question of fact. Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). When a question regarding the adequacy of the written description arises, the fundamental factual inquiry is whether the specification conveys to those skilled in the art, as of the filing date sought, that applicant was in possession of the invention being claimed. Section 2163.02 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). Possession can be shown in a number of ways. For

example, an Applicant can show possession by: (1) an actual reduction to practice of the claimed invention; (2) a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention; or (3) any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. Section 2163.04 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention as defined by the claims. *Id.* "A general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description." *Id.* The *Manual of Patent Examining Procedure* even cautions Examiners that "rejection of an original claim for lack of written description should be rare." (See Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003)).

The U.S. PTO has issued Guidelines governing its internal practice for assessing whether the specification contains an adequate written description of the invention being claimed. In its Guidelines, the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics..., i.e., the complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, January, 2001 *Guidelines*, 66 Fed. Reg. at 1106.

Contrary to the arguments made by the Examiner, Applicants submit that the specification adequately describes the polynucleotides encompassed within the scope of the invention being claimed. First, as specifically recommended by the *Guidelines*, Applicants have provided the complete structure of the claimed polynucleotides as demonstrated in SEQ ID NOS: 15 and 16. Second, with respect to the issue raised by the Examiner regarding the numerous structural variants, Applicants submit that because the level of skill in the area of molecular biology is considerably high, one of ordinary skill in the art, after reviewing Applicants' specification, would clearly recognize that the Applicants have provided an adequate written description of the variants, substitutions, deletions and/or additions encompassed by the claims. Applicants specifically direct the Examiner's attention to page 25, lines 16-28 of the specification where it states that "Thus a polypeptide of the present invention may have an amino acid sequence that is identical to that of the naturally occurring polypeptide or that is different by minor variations due to one or more amino acid substitutions. The variation may be a "conservative change" typically in the range of about 1 to 5 amino acids, wherein the substituted amino acid has similar structural or chemical properties, e.g., replacement of leucine with isoleucine or threonine with serine. In contrast, variations may include nonconservative changes, e.g., replacement of a glycine with a tryptophan. Similar minor variations may also include amino acid deletions or insertions, or both. Guidance in determining which and how many amino acid residues may be substituted, inserted or deleted without changing biological or immunological activity may be found using computer programs well known in the art, for example, DNASTAR software (DNASTAR Inc., Madison, WI)." As illustrated by the above cited portion of the specification, computer programs are available to those of ordinary skill in the art and these programs can be used in providing guidance in determining "which and how" many amino acids residues in the polypeptides that are derived from polynucleotides SEQ ID NOS: 15 and 16, can be substituted, inserted or deleted. The use of such programs is well known to those of ordinary skill in the art.

Additionally, page 11, line 21 to page 12, line 5 of the specification describes that methods for determining the percent identity are well known in the art.

Therefore, in view of the aforementioned arguments, Applicants submit that one of ordinary skill in the art would clearly recognize that Applicants had possession of the claimed invention and have provided an adequate written description. Thereupon, Applicants respectfully submit that the Examiner has failed to provide sufficient factual evidence to rebut the presumption that the description as filed is inadequate. Moreover, the Examiner fails to present any factual evidence as to why a person of ordinary skilled in the art would not recognize in Applicants disclosure a description of the invention as defined by the claims. In view of the absence of such evidence, Applicants submit that this rejection should be withdrawn.

Applicants submit, therefore, that the specification is adequately written under 35 U.S.C. § 112, first paragraph. For these reasons, Applicants respectfully request withdrawal of the rejection of claims 10-16, 33, 35, 38 and 39 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 10-16 and 33 Under 35 U.S.C. § 102(b)

Claims 10-16 and 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gibco/BRL (1993/1994), p. 7-18 (herein "Gibco/BRL").

The Examiner provides four examples of sequences that are 16 nucleotides in length from the sequence designated PUC 19 (found in Genbank Accession No. M77789). It seems that the Examiner is inferring that these sequences are "fragments" and provides an alignment of these sequences to some of the instant sequences, SEQ ID NOS: 1-4, showing a percent identity of more than 50% based on the length of the 16 nucleotides. The Examiner then states that since PUC 19 is a polynucleotide that is 2886 nucleotides in length, it is more than 10 nucleotides in length. Thus, the Examiner concludes that claims 10-16 and 33 are anticipated by Gibco/BRL. Applicants respectfully traverse the rejection.

The claims previously recited "at least one polynucleotide having at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS: 1-16, and fragments or complements thereof, wherein said fragments have a length of at least 10 nucleotides" (emphasis added). The claims do not recite "a portion of a polynucleotide having at least 50% identity to SEQ ID NOS: 1-16" as the Examiner is interpreting.

As the Examiner states, Gibco/BRL discloses a polynucleotide that is 2886 nucleotides in length (PUC 19). It is noted that Gibco/BRL discloses that this polynucleotide has multiple cloning sites. However, Gibco/BRL does not disclose any fragments that are separate from the PUC 19 polynucleotide that is 2886 nucleotides in length. Instead, the Examiner is referring to the portions of the sequence as a "fragment" which is improper.

In the first sequence example the Examiner extracted from Gibco/BRL, the Examiner states that "PUC is a polynucleotide that is 2886 nucleotides in length thereby being larger than 10 nucleotides, which polynucleotide comprises at least one fragment of 16 nucleotides that is 62.5% identical with SEQ ID NO: 1". It is inconsistent to state that a polynucleotide that is 2886 nucleotides in length is considered to meet Applicants' claim language of a "fragment" and then compare only 16 nucleotides of the 2886 nucleotides for percent identity. The Examiner has only shown 10 nucleotides alignment in his first example. Since Gibco/BRL does not disclose any fragments, the percent identity must be compared to the 2886 nucleotides from PUC 19 or to the 258 nucleotides from SEQ ID NO: 1, not the 16 nucleotides. Therefore, at best there is only 3.9% identity (10 divided by 258) with respect to the Examiner's first example. The three other examples which the Examiner provides from Gibco/BRL's PUC 19 polynucleotide do not meet the claim language in a similar manner.

However, in an effort to expedite prosecution of the instant application, the claims have been amended to require the fragments to be at least 15 nucleotides in length. Support for this amendment can be found in the specification on page 13, lines 17-22. Additionally, Applicants have limited the polynucleotide sequences to be SEQ ID NOS: 15 and 16.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 10-16 and 33 under 35 U.S.C. § 102(b) as being anticipated by Gibco/BRL (1993/1994), p. 7-18.

Rejection of Claims 10-16, 33 and 35 Under 35 U.S.C. § 103(a)

Claims 10-16, 33 and 35 are rejected under 35 U.S.C. § 103(b) as being unpatentable over Guthrie *et al.*, U.S. Patent No. 5,262,318 (herein "Guthrie) in view of Stratagene catalog (1988), p. 39 (herein "Stratagene").

It appears that the Examiner meant the claims to be rejected over Gibco/BRL as previously applied, in view of Guthrie and Stratagene since the Examiner refers to the PUC19 polynucleotide, neither Guthrie nor Stratagene appear to disclose this designated polynucleotide, and the Examiner further states that PUC19 meets the nucleic acid requirement of the claimed invention since it comprises nucleic acids greater than 10 nucleotides which are at least 50% identical to SEQ ID NOS: 1-16. The Examiner applies Guthrie for teaching of cell transformation and Stratagene for teaching cloning. Applicants respectfully traverse the rejection.

As noted above Gibco/PRL does not disclose or suggest the claimed polynucleotides. Applicants' arguments above are incorporated herein. It is clear that Guthrie and Stratagene do not cure the deficiencies of Gibco/PRL. For these reasons, Applicants respectfully request withdrawal of the rejection of claims 10-16, 33 and 35 under 35 U.S.C. § 103(b) as being unpatentable over Guthrie et al., U.S. Patent No. 5,262,318 in view of Stratagene catalog (1988), p. 39.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

Billing-Medel, *et al.*

Wood, Phillips, Katz, Clark & Mortimer
500 West Madison Street
Suite 3800
Chicago, IL 60662-2511

Tel.: (312) 876-2109
Fax.: (312) 876-2020

Dinh X. Nguyen
Registration No. 54,923
Attorney for Applicants